Inspections of CBER-Regulated Products

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Overview of Inspections

- **Who performs inspections?**
  - CBER, ORA HQ, ORA District, OCI
- **When are inspections performed?**
  - Prior to marketing; post-market
- **What instructions guide the process?**
- **How are findings reported?**

Who Performs Inspections?

- It all depends... “Team Biologics” charter - strategic approach to integrating science into inspections
- For different industries, the “lead” role may belong to different FDA units - Strong, scientific risk-based component to inspections of our products

Who Performs Inspections?

- **CBER's DMPQ or OBRR lead for Pre-license/pre-approval**
  - licensed biological drugs/devices
- **ORA District lead for devices w/ PMAs, 510(k)**
- **ORA Team Biologics Core Team for licensed products**
- **Office of Criminal Investigations**

When Are Inspections Performed?

- Post-marketing:

  - Biennial Inspections to determine compliance with application commitments, 21 CFR 600 and 211 or 820

  - on specific assignment from OCBQ for (a) investigation of complaints or adverse event reports, or (b) surveillance of industry segments

When Are Inspections Performed?

- Prior to marketing = Bioresearch monitoring (BIMO): 21CFR50, 56, 312

  - to verify accuracy of application data and for human subject protection

  - on specific assignments from OCBQ's BIMO branch when BLA (or PMA) has been filed

  - on specific assignment from OCBQ's BIMO branch for (a) investigation of complaints or adverse event reports, or (b) surveillance of active INDs

What Instructions Guide the Process

- ORA workplan – developed by ORA and CBER based on Congressional budget, FDA's Strategic Plan, and newly emerging public health concerns
  - firm-specific or industrywide concerns
- Compliance Programs
- Guidance Documents

How Are Findings Reported?

- Establishment Inspection Report (EIR) &FDA-483 List of Observations
- Field Management Directive (FMD) 145 – can get copy of EIR (minor deletions) unless...
- Freedom of Information (FOI) Act – others can get redacted EIR
- Field Accomplishment and Compliance Tracking System (FACTS): who, when, what covered, findings, recommended f/u, reinspection date
  - BIMO reports classified by the Center

How Are Findings Reported?

- Discuss inspection findings (a) w/ FDA Investigator during inspection to minimize chance for misunderstandings, and (b) with your management to develop corporate response plan prior to FDA-483
- Multi-site establishment: Be aware of findings at other locations... they could apply to your plant
- Contractors, including manufacturers of clinical supplies: Be aware of results of their inspections

Inspections of CBER-Regulated Products

- A well thought out Quality Assurance program incorporating a systems-approach to your activities is the best way to promote and protect the public health while minimizing the chance for an unfavorable FDA inspection.
- Ask us what we think.